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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0179; FRL-9995-63]

Sulfoxaflor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfoxaflor in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR–4) and Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0179, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0179 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0179, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of April 23, 2014 (79 FR 22602) (FRL-9907-39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8237) by Dow AgroSciences, LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested to establish tolerances in 40 CFR part 180 for residues of the insecticide, sulfoxaflor (*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-λ^4-sulfanylidene]cyanamide), in or on alfalfa, forage at 7 parts per million (ppm); alfalfa, hay at 20 ppm; alfalfa, seed at 30 ppm; alfalfa, silage at 9 ppm; animal feed, non-grass, group 18, forage at 15 ppm; animal feed, non-grass, group 18, hay at 20 ppm; animal feed, non-grass, group 18, silage at 9 ppm; buckwheat, forage at 1 ppm; buckwheat, grain at 0.08 ppm; buckwheat, hay at 1.5 ppm; buckwheat, straw at 2 ppm; cacao bean, dried bean at 0.15 ppm; clover forage at 15 ppm; clover hay at 20 ppm; clover silage at 8 ppm; corn, field, forage at 0.5 ppm; corn, field, grain at 0.015 ppm; corn, field, stover at 0.8 ppm; corn, pop at 0.015 ppm; corn, pop, stover at 0.8 ppm; corn, sweet, at 0.01 ppm; corn, sweet, forage at 0.6 ppm; corn, sweet, stover at 0.7 ppm; millet, forage at 0.4 ppm; millet, grain at 0.3 ppm; oat, grain at 0.4 ppm; oat, hay at 1 ppm; oat, straw at 2 ppm; pineapple at 0.09 ppm; rye, forage at 1 ppm; rye, grain at 0.08 ppm; rye, hay at 1.5 ppm; rye, straw at 2 ppm; sorghum, forage at 0.4 ppm; sorghum, grain at 0.3 ppm; sorghum, stover at 0.9 ppm; teff, forage at 1 ppm; teff, grain at 0.08 ppm; teff, hay at 1.5 ppm; teff, straw at 2 ppm; teosinte, grain at 0.015 ppm; triticale, forage at 1 ppm; triticale, grain at 0.08 ppm; triticale, hay at 1.5 ppm; and triticale, straw at 2 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in docket number EPA-HQ-OPP-2014-0156, *http://www.regulations.gov*. The petition also requested revisions to the certain existing animal commodity tolerances, as follows: milk at 1

ppm; fat of cattle, goat, horse and sheep at 0.6 ppm; meat of cattle, goat, horse and sheep at 1 ppm; meat byproducts of cattle, goat, horse and sheep at 2.5 ppm; hog, fat at 0.04 ppm; hog, meat at 0.07 ppm; hog, meat byproducts at 0.2 ppm; egg at 0.08 ppm; poultry, meat at 0.09 ppm; poultry, fat at 0.03 ppm; poultry, meat byproducts at 0.2 ppm. These requested revisions were inadvertently omitted from the April 23, 2014 **Federal Register** notice (79 FR 22602) (FRL-9907-39) but were included in the summary of the petition that was available in the docket. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

In the **Federal Register** of July 24, 2018 (83 FR 34968) (FRL-9980-31), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8666) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of sulfoxaflor (*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]-λ^4-sulfanylidene]cyanamide) in or on the following raw agricultural commodities: artichoke, globe at 0.70 ppm; asparagus at 0.015 ppm; brassica, leafy greens, subgroup 4–16B, except watercress at 2.0 ppm; bushberry subgroup 13-07B at 2.0 ppm; caneberry subgroup 13-07A at 1.5 ppm; celtuce at 2.0 ppm; florence fennel at 2.0 ppm; fruit, stone, group 12-12 at 3.0 ppm; kohlrabi at 2.0 ppm; leafy greens subgroup 4-16A at 6.0 ppm; leaf petiole vegetable subgroup 22B at 2.0 ppm; nut, tree, group 14-12 at 0.015 ppm; sunflower subgroup 20B at 0.30 ppm; and vegetable, brassica, head and stem, group 5-16, except cauliflower at 2.0 ppm. Additionally, the petition requested to amend 40 CFR 180.668 by removing the established tolerances for residues of sulfoxaflor in or on the following raw agricultural commodities: fruit, stone, group 12 at 3.0

ppm; leafy greens, subgroup 4A at 6.0 ppm; leafy petiole, subgroup 4B at 2.0 ppm; nuts, tree, group 14 at 0.015 ppm; pistachio at 0.015 ppm; and vegetable, brassica, leafy, group 5, except cauliflower at 2.0 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in docket number EPA-HQ-OPP-2018-0179, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested (PP 8E8666), as authorized under FFDCA section 408(d)(4)(A)(i). Also, the petitioner withdrew the tolerances proposed for buckwheat and clover (PP 4F8237). Since clover is a representative commodity for non-grass animal feeds (group 18), a crop group tolerance cannot be established for that crop group. Additionally, existing tolerances for livestock commodities (e.g. cattle, goats, sheep, and horse) are being revised based upon a recalculation of the livestock dietary burden. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants

and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfoxaflor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfoxaflor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Specific information on the studies received and the nature of the adverse effects caused by sulfoxaflor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of May 17, 2013 (78 FR 29041) (FRL-9371-4). Further discussion of the toxicological profile for sulfoxaflor can be found at http://*www.regulations.gov* in section 4.0 titled "*Hazard Characterization and Dose-Response Assessment*" (pages 14-28) of the document titled "*Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Avocado and Rice"* and pages 13-26 of the document titled "*Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Artichoke, Asparagus, Bushberry, Caneberry and Sunflower, and Multiple Crop Group Conversions*" in docket ID number EPA-HQ-OPP-2018-0179.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide.*

A summary of the toxicological endpoints for sulfoxaflor used for human risk assessment is shown in the table of this unit.

Table - - Summary of Toxicological Doses and Endpoints for Sulfoxaflor for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-49 years of age)	NOAEL = 1.8 mg/kg/day UF_A = 3x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.06 mg/kg/day aPAD = 0.06 mg/kg/day	Developmental Neurotoxicity Study (DNT) LOAEL = 7.1 mg/kg/day based on decreased neonatal survival (PND 0-4).

Acute dietary (General population including infants and children)	NOAEL = 25 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day	Acute Neurotoxicity Study LOAEL = 75 mg/kg/day based on decreased motor activity.
Chronic dietary (All populations)	NOAEL= 5.13 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day cPAD = 0.05 mg/kg/day	Chronic/Carcinogenicity Study - Rat LOAEL = 21.3 mg/kg/day based on liver effects including increased blood cholesterol, liver weight, hypertrophy, fatty change, single cell necrosis and macrophages.
Cancer (Oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenic Potential." Quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to sulfoxaflor.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to sulfoxaflor, EPA considered exposure under the petitioned-for tolerances as well as all existing sulfoxaflor tolerances in 40 CFR 180.668. EPA assessed dietary exposures from sulfoxaflor in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for sulfoxaflor. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute assessment was based on the

maximum observed residue levels from crop field trials and 100 percent crop treated (PCT).

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic assessment assumed average field trial residues and 100 PCT.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that quantification of risk using a non-linear approach (i.e., RfD/cPAD) will adequately account for all chronic toxicity, including carcinogenicity. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sulfoxaflor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sulfoxaflor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Environmental fate data indicate that the use of sulfoxaflor is likely to result in different residue profiles in surface water and ground water. The residues in surface water are likely to include parent sulfoxaflor and X11719474/X11519540 degradates while X11719474/X11519540 will predominate in ground water. When the residue profiles are coupled with the toxicological database, it becomes apparent that the EDWCs for assessing acute dietary exposure for the general population, acute dietary exposure for women of child-bearing age, and chronic dietary exposure for all populations need to be addressed differently. An explanation of the three scenarios and the rationale for the approaches taken by EPA is provided below.

Acute Exposure: Separate acute endpoints were selected for the general population and females 13 to 49 years of age. For the general population, the point of departure is based on decreased motor activity observed in the acute neurotoxicity study. As there are no data available to examine the potency of X11719474 and X11519540 with respect to this endpoint, EPA has assumed that the two metabolites possess similar toxicity relative to sulfoxaflor in order to assess acute dietary risk for the general population. The EDWC for ground water is significantly greater than the acute estimate for surface water and, per Agency policy, is being used in the acute dietary assessment for the general population. As it is a ground water EDWC, it represents residues of the metabolites.

For females 13 to 49 years of age, the developmental endpoint of increased neonatal deaths was chosen because a single exposure during late gestation can adversely affect the developing fetus via agonism of the muscle nicotinic acetylcholine receptor (nAChR), and the age group represents women of child-bearing age. Studies with the metabolite X11719474 demonstrated that it does not cause agonism of the fetal rat muscle nAChR. Based on structural similarity between X11719474 and X11519540, the Agency further determined that X1159540 is

not likely to result in agonism of the muscle nAChR. Therefore, both metabolites have been excluded from assessment scenarios using the developmental endpoint. Since the ground water EDWC represents residues of only these metabolites, the acute surface water EDWC, which consists of only parent sulfoxaflor, is the appropriate estimate for assessing dietary exposure for women of child-bearing age.

Chronic Exposure: The endpoint for assessing chronic dietary exposure is hepatotoxicity. The Agency has determined that it is appropriate to combine residues of sulfoxaflor, X11719474, and X11519540 when assessing chronic exposure and, furthermore, there is sufficient evidence to adjust the assessment to account for the different potencies of the metabolites. Based on NOAELs in the 28-day oral toxicity studies in rats, the potencies of the metabolites, relative to sulfoxaflor, are 0.3X for X11719474 and 3.4X for X11519540. To account for the relative toxicity, the EDWCs for each metabolite are multiplied by their respective potency factors.

EDWCs Used in the Assessment: For the acute dietary risk assessment of the general population, the groundwater EDWC is greater than the surface water EDWC and was used in the assessment. The residue profile in groundwater is 12 ppb X11719474 and 1.6 ppb X11519540 (totaling 13.6 ppb). Parent sulfoxaflor is not expected in groundwater. For this assessment, the regulatory toxicological endpoint is based on neurotoxicity. There is no information to relate the neurotoxicity of the metabolites to that of sulfoxaflor; therefore, no toxicity adjustment was made to the EDWC.

For the acute dietary risk assessment of females 13 to 49, the regulatory endpoint is attributable only to the parent compound (as previously discussed); therefore, the surface water EDWC is the most appropriate EDWC for this assessment even though it is of a lower value than

the groundwater EDWC, which reflects metabolites only. The EDWC of 9.2 ppb was used and no toxicological adjustment was made.

For the chronic dietary risk assessment, the toxicological endpoint is liver effects, for which it is possible to account for the relative toxicities of X11719474 and X11519540 as compared to sulfoxaflor. The groundwater EDWC is greater than the surface water EDWC. The residue profile in groundwater consists of 8 ppb X11719474 and 1.1 ppb X11519540. Adjusting for the relative toxicity results in 2.4 ppb equivalents of X11719474 and 3.7 ppb X11519540 (totaling 6.1 ppb). The adjusted groundwater EDCW is greater than the surface water EDWC and was, therefore, used to assess the chronic dietary exposure scenario.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Sulfoxaflor is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found sulfoxaflor to share a common mechanism of toxicity with any other substances, and sulfoxaflor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sulfoxaflor does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to

evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Developmental/offspring toxicity, manifested as skeletal abnormalities and neonatal deaths, was observed in rats only. The skeletal abnormalities, forelimb flexure, bent clavicles, and hindlimb rotation likely result from skeletal muscle contraction due to agonism of the muscle nAChR *in utero*. Similarly, contraction of the diaphragm muscle prevents normal breathing in neonates resulting in increased mortality. The skeletal abnormalities were observed at high doses in the developmental and reproduction studies and decreased neonatal survival was consistently observed in the reproduction and developmental neurotoxicity studies. These developmental effects were not observed in the rabbit.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is

based on the following findings:

i. The toxicity database for sulfoxaflor is complete.

ii. In the acute neurotoxicity study, decreased motor activity and clinical signs associated with neurotoxicity (increased muscle tremors and twitches, convulsions, hindlimb splaying, increased lacrimation and salivation, decreased pupil size and response to touch, gait abnormalities and decreased rectal temperature) were observed. However, the level of concern for neurotoxicity is low because (1) the effects are well characterized; (2) the dose-response curve for these effects is well characterized; (3) clear NOAELs have been identified; and (4) the endpoints chosen for risk assessment are protective for the observed neurotoxicity.

iii. Although there was quantitative susceptibility observed in the DNT and developmental rat studies, there is no residual uncertainty because (1) the effects are well characterized; (2) clear NOAELs were identified; and (3) the endpoints chosen for risk assessment are protective of potential *in utero* and developmental effects. Quantitative susceptibility in the DNT was based on an increased rate of neonatal deaths at a dose where no maternal toxicity was observed. Quantitative susceptibility was also observed in the developmental rat study as decreased fetal weight, forelimb flexure, hindlimb rotation, and bent clavicles at a dose that did not cause maternal toxicity. However, the apparent enhanced sensitivity in this study may be due to the limited number of evaluations conducted in dams in the study rather than a true sensitivity of the young. In that regard, adverse liver effects were observed in the 90-day rat study at a LOAEL lower than the highest dose tested in the developmental rat study. The dams in the developmental rat study had increased liver weights but clinical chemistry and liver histopathological analysis were not investigated to determine if the effects on the liver were adverse. Qualitative susceptibility was observed in the two-

generation reproduction study since neonatal deaths were observed at the same dose that resulted in hepatotoxicity in parental animals. However, these effects occurred at a higher dose compared to the offspring effects observed in the DNT. Finally, there was no evidence of quantitative or qualitative susceptibility in the developmental studies in the rabbit.

iv. There are no residual uncertainties with regard to dietary exposure. The dietary exposure assessments are based on high-end residue estimates, processing factors, and 100 PCT, as well as upper-bound modeled estimates of residues in drinking water. These assessments will not underestimate the exposure and risks posed by sulfoxaflor.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfoxaflor will occupy 28% of the aPAD for both children 1 to 2 years old and females 13 to 49 years old, the population groups receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfoxaflor from food and water will utilize 47% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

3. *Short- and Intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Short- and intermediate-term adverse effects were identified; however, sulfoxaflor is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for sulfoxaflor**.**

4. *Aggregate cancer risk for U.S. population*. EPA assessed cancer risk using a non-linear approach (i.e., RfD) since it adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to sulfoxaflor. As the chronic dietary endpoint and dose are protective of potential cancer effects, sulfoxaflor is not expected to pose an aggregate cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

High performance liquid chromatographic methods with positive-ion electro spray

interface (ESI) and tandem mass spectrometric detection (LC/MS/MS) were previously reviewed and found to be acceptable for tolerance enforcement of sulfoxaflor residues (the two metabolites, X11719474 and X11721061, are also quantitated). The limit of quantitation (LOQ), determined as the lowest level of method validation (LLMV), is 0.010 ppm in all matrices.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex has established MRLs for residues of sulfoxaflor on broccoli (3 ppm) and head cabbage (0.4 ppm). These commodities are covered in the U.S. crop group 5-16 (vegetable, brassica, head and stem), for which EPA is establishing a tolerance at 2 ppm in this rulemaking. This 2 ppm tolerance is part of a conversion from the existing group 5A, including broccoli and cabbage, to the new crop group 5-16. The old group was not harmonized with the Codex MRL.

EPA is not harmonizing the new crop group 5-16 either because the representative commodity data for the new group 5-16 support establishing one tolerance level for all commodities in the group rather than a higher broccoli and lower cabbage tolerance.

In addition, Codex has established MRLs for leafy vegetables at 6 ppm. EPA's leafy vegetable crop group 4-16 is split into two subgroups: 4-16A for leafy greens and 4-16B for Brassica, leafy greens. Although EPA is establishing a subgroup 4-16A tolerance at 6 ppm, which harmonizes with the Codex MRL, EPA is also establishing a subgroup 4-16B tolerance at 2 ppm, which is not harmonized with the Codex MRL. This is because the representative commodity data for mustard greens indicates that lower residues of the pesticide are present on the brassica, leafy greens commodities.

The tolerances in meat and meat byproducts of hogs and poultry are being harmonized with the corresponding Codex MRLs instead of the levels proposed by the petitioner. Therefore, tolerances in hog meat and hog meat byproducts are being established at 0.3 and 0.6 ppm, respectively (rather than 0.07 and 0.2 ppm), in order to harmonize with MRLs of 0.3 mg/kg in meat from mammals other than marine mammals, and 0.6 mg/kg in mammalian edible offal. Similarly, tolerances in poultry meat and poultry meat byproducts are being established at 0.1 and 0.3 ppm, respectively (rather than 0.09 and 0.2 ppm), in order to harmonize with Codex MRLs of 0.1 mg/kg in poultry meat, and 0.3 ppm in poultry edible offal.

C. Response to Comments

Thirteen comments were received in response to the NOF for petition 4F8237. Nine of these comments were primarily related to bee toxicity, which is not an issue that is relevant to the Agency's evaluation of safety of the sulfoxaflor tolerances under section 408 of the FFDCA, which requires the Agency to evaluate the potential harms to human health, not effects on the

environment.

Another four comments were primarily related to a general disapproval of pesticides in general. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these sulfoxaflor tolerances are safe. The commenters have provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

The Agency is establishing a tolerance of 0.01 ppm in asparagus as opposed to the 0.015 ppm proposed by the petitioner. In the field trials that serve as the basis for the tolerance level, the application rates were exaggerated by 4.2-6.5X the proposed application rate, and the resulting residues in all but one trial were <0.01 ppm and in the other trial the residues measured 0.011 ppm. When sulfoxaflor is used in accordance with the proposed label, all residues are expected to be <0.01 ppm. Therefore, the Agency is establishing the tolerance at the limit of quantification (0.01 ppm).

Tolerances are not being established in clover or buckwheat commodities (as these proposed new uses were subsequently withdrawn by the registrant after submission of the original petition), nor in non-grass feeds (group 18), for which clover is a representative commodity.

In order to maximize global regulatory harmonization, it became EPA policy in April 2011 to use the OECD calculation procedures to derive tolerance levels. As such, the proposed

tolerance of 0.9 ppm in sorghum, grain, stover will be listed as 1 ppm; the proposed tolerance of 30 ppm in alfalfa seed will be changed to 40 ppm; the proposed tolerance of 0.09 ppm in pineapple will be changed to 0.1 ppm; and the proposed tolerance of 0.15 ppm in cacao, dried bean will be changed to 0.05 ppm.

For millet, there is no established "parent" millet term that covers more than one millet. As such, the tolerances are being established specifying both proso and pearl millet individually.

Tolerances of 0.6 and 2.5 ppm in the fat and meat byproducts, respectively, of cattle, goats, horses and sheep were proposed by the petitioner. However, revised tolerances of 0.2 and 0.8 ppm in these fat and meat byproducts are appropriate since the clover use was withdrawn, resulting in a lower dietary burden to livestock and lower anticipated residues in livestock commodities than originally considered by the petitioner.

Existing tolerances in cattle, meat; goat, meat; sheep, meat; and horse, meat is being revised in this action to 0.4 ppm, consistent with anticipated residues based upon a recalculated dietary burden of sulfoxaflor, and the results of a lactating dairy cattle feeding study.

For several commodities in the IR-4 petition (PP 8E8666), the requested tolerances include an additional significant figure (such as 1.0 ppm rather than 1 ppm). EPA is establishing the tolerances without the trailing zero to be consistent with current rounding practice.

E. International Trade Considerations

In this final rule, EPA is reducing the existing tolerances for arugula; cress, garden; and cress, upland from 6 ppm to 2 ppm. Currently, these commodities are included in leafy greens subgroup 4A, which has a tolerance of 6 ppm. In 2016, EPA moved these commodities to the Brassica leafy greens subgroup 4-16B. (81 FR 26471; FRL-9944-87 (May 3, 2016)). In today's rule, EPA is establishing a tolerance for residues of sulfoxaflor in or on commodities in Brassica

leafy greens subgroup 4-16B, which now includes arugula, garden cress, and upland cress, at 2 ppm, based on available residue data. This results in a reduction of tolerance levels for these three commodities.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of this revision. In addition, the SPS Agreement requires that members provide a ''reasonable interval'' between the publication of a regulation subject to the agreement and its entry into force to allow time for producers in exporting member countries to adapt to the new requirement. At this time, EPA is establishing an expiration date for the existing tolerances to allow those tolerances to remain in effect for a period of six months after the effective date of this final rule, in order to address the requirement to provide a reasonable interval. After the six-month period expires, residues of sulfoxaflor on arugula; cress, garden; and cress, upland cannot exceed the newly established tolerances of 2 ppm.

This reduction in tolerance levels is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of sulfoxaflor in or on Alfalfa, forage at 7 ppm; Alfalfa, hay at 20 ppm; Alfalfa, seed at 40 ppm; Alfalfa, silage at 9 ppm; Artichoke, globe at 0.7 ppm; Asparagus at 0.01 ppm; Brassica, leafy greens, subgroup 4-16B, except watercress at 2 ppm; Bushberry subgroup 13-07B at 2 ppm; Cacao, dried bean at 0.05 ppm; Caneberry subgroup 13-07A at 1.5 ppm; Celtuce at 2 ppm; Corn, field, forage at 0.5 ppm; Corn, field, grain at 0.015 ppm; Corn, field, stover at 0.8 ppm; Corn, pop, grain at 0.015 ppm; Corn,

pop, stover at 0.8 ppm; Corn, sweet, forage at 0.6 ppm; Corn, sweet, kernel plus cob with husks removed at 0.01 ppm; Corn, sweet, stover at 0.7 ppm; Fennel, Florence, fresh leaves and stalk at 2 ppm; Fruit, stone, group 12-12 at 3 ppm; Kohlrabi at 2 ppm; Leaf petiole vegetable subgroup 22B at 2 ppm; Leafy greens subgroup 4-16A at 6 ppm; Millet, proso, forage at 0.4 ppm; Millet, pearl, forage at 0.4 ppm; Millet, proso, grain at 0.3 ppm; Nut, tree, group 14-12 at 0.015 ppm; Oat, grain at 0.4 ppm; Oat, hay at 1 ppm; Oat, straw at 2 ppm; Pineapple at 0.1 ppm; Rye, forage at 1 ppm; Rye, grain at 0.08 ppm; Rye, hay at 1.5 ppm; Rye, straw at 2 ppm; Sorghum, grain, forage at 0.4 ppm; Sorghum, grain, grain at 0.3 ppm; Sorghum, grain, stover at 1 ppm; Sunflower subgroup 20B at 0.3 ppm; Teff, forage at 1 ppm; Teff, grain at 0.08 ppm; Teff, hay at 1.5 ppm; Teff, straw at 2 ppm; Teosinte, grain at 0.015 ppm; Triticale, forage at 1 ppm; Triticale, grain at 0.08 ppm; Triticale, hay at 1.5 ppm; Triticale, straw at 2 ppm; and Vegetable, brassica, head and stem, group 5-16, except cauliflower at 2 ppm.

Additionally, the following existing tolerances are revised as follows: Cattle, fat at 0.2 ppm; Cattle, meat at 0.4 ppm; Cattle, meat byproducts at 0.8 ppm; Egg at 0.06 ppm; Goat, fat at 0.2 ppm; Goat, meat at 0.4 ppm; Goat, meat byproducts at 0.8 ppm; Hog, fat at 0.03 ppm; Hog, meat at 0.3 ppm; Hog, meat byproducts at 0.6 ppm; Horse, fat at 0.2 ppm; Horse, meat at 0.4 ppm; Horse, meat byproducts at 0.8 ppm; Milk at 0.3 ppm; Poultry, fat at 0.02 ppm; Poultry, meat at 0.1 ppm; Poultry, meat byproducts at 0.3 ppm; Sheep, fat at 0.2 ppm; Sheep, meat at 0.4 ppm; and Sheep, meat byproducts at 0.8 ppm.

The established tolerances for Fruit, stone, group 12; Leafy greens, subgroup 4A; Leafy petiole, subgroup 4B; Nuts, tree, group 14; Pistachio; and Vegetable, Brassica, leafy, group 5, except cauliflower are removed as unnecessary due to the establishment of the above tolerances.

Lastly, in order to provide a reasonable interval for implementation of certain tolerances

being reduced through this rule, EPA is leaving in place the following individual tolerances for a period of six months: arugula; cress, garden; and cress, upland.

VI. Statutory and Executive Order Reviews

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 12, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.668, amend the table in paragraph (a) as follows:

a. Add alphabetically the entries Alfalfa, forage; Alfalfa, hay; Alfalfa, seed; Alfalfa, silage; Artichoke, globe; Arugula; Asparagus; *Brassica*, leafy greens, subgroup 4-16B, except watercress; Bushberry subgroup 13-07B; Cacao, dried bean; Caneberry subgroup 13-07A; Celtuce; Corn, field, forage; Corn, field, grain; Corn, field, stover; Corn, pop, grain; Corn, pop, stover; Corn, sweet, forage; Corn, sweet, kernel plus cob with husks removed; Corn, sweet, stover; Cress, garden; Cress, upland; Fennel, Florence, fresh leaves and stalk; Fruit, stone, group 12-12; Kohlrabi; Leaf petiole vegetable subgroup 22B; Leafy greens subgroup 4-16A; Millet, proso, forage; Millet, pearl, forage; Millet, proso, grain; Millet, pearl, grain; Nut, tree, group 14-12; Oat, grain; Oat, hay; Oat, straw; Pineapple; Rye, forage; Rye, grain; Rye, hay; Rye, straw; Sorghum, grain, forage; Sorghum, grain, grain; Sorghum, grain, stover; Sunflower subgroup 20B; Teff, forage; Teff, grain; Teff, hay; Teff, straw; Teosinte, grain; Triticale, forage; Triticale, grain; Triticale, hay; Triticale, straw; and Vegetable, *brassica*, head and stem, group 5-16, except cauliflower;

b. Revise the entries for Cattle, fat; Cattle, meat; Cattle, meat byproducts; Goat, fat; Goat, meat; Goat, meat byproducts; Hog, fat; Hog, meat; Hog, meat byproducts; Horse, fat; Horse, meat; Horse, meat byproducts; Milk; Poultry, eggs; Poultry, fat; Poultry, meat; Poultry, meat byproducts; Sheep, fat; Sheep, meat; and Sheep, meat byproducts; and

c. Remove the entries for Fruit, stone, group 12; Leafy greens, subgroup 4A; Leafy

petiole, subgroup 4B; Nuts, tree, group 14; Pistachio; and Vegetable, *Brassica*, leafy, group 5, except cauliflower.

The revisions and additions read as follows:

§ 180.668 Sulfoxaflor; tolerances for residues

(a) * * *

Commodity	Parts per million
Alfalfa, forage	7
Alfalfa, hay	20
Alfalfa, seed	40
Alfalfa, silage	9
* * * * * * *	
Artichoke, globe	0.7
Arugula [1]	6
Asparagus	0.01
* * * * * * *	
Brassica, leafy greens, subgroup 4-16B, except watercress	2
Bushberry subgroup 13-07B	2
Cacao, dried bean	0.05
Caneberry subgroup 13-07A	1.5
Cattle, fat	0.2
Cattle, meat	0.4
Cattle, meat byproducts	0.8
* * * * * * *	
Celtuce	2
* * * * * * *	
Corn, field, forage	0.5
Corn, field, grain	0.015
Corn, field, stover	0.8
Corn, pop, grain	0.015
Corn, pop, stover	0.8
Corn, sweet, forage	0.6
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.7
* * * * * * *	
Cress, garden [1]	6
Cress, upland [1]	6
* * * * * * *	
Egg	0.06

Fennel, Florence, fresh leaves and stalk	2
* * * * * * *	
Fruit, stone, group 12-12	3
Goat, fat	0.2
Goat, meat	0.4
Goat, meat byproducts	0.8
* * * * * * *	
Hog, fat	0.03
Hog, meat	0.3
Hog, meat byproducts	0.6
Horse, fat	0.2
Horse, meat	0.4
Horse, meat byproducts	0.8
Kohlrabi	2
Leaf petiole vegetable subgroup 22B	2
Leafy greens subgroup 4-16A	6
Milk	0.3
* * * * * * *	
Millet, proso, forage	0.4
Millet, pearl, forage	0.4
Millet, proso, grain	0.3
Millet, pearl, grain	0.3
Nut, tree, group 14-12	0.015
Oat, grain	0.4
Oat, hay	1
Oat, straw	2
* * * * * * *	
Pineapple	0.1
Poultry, fat	0.02
Poultry, meat	0.1
Poultry, meat byproducts	0.3
* * * * * * *	
Rye, forage	1
Rye, grain	0.08
Rye, hay	1.5
Rye, straw	2
Sheep, fat	0.2
Sheep, meat	0.4
Sheep, meat byproducts	0.8
Sorghum, grain, forage	0.4
Sorghum, grain, grain	0.3
Sorghum, grain, stover	1
* * * * * * *	
Sunflower subgroup 20B	0.3

Teff, forage	1
Teff, grain	0.08
Teff, hay	1.5
Teff, straw	2
Teosinte, grain	0.015
* * * * * * *	
Triticale, forage	1
Triticale, grain	0.08
Triticale, hay	1.5
Triticale, straw	2
Vegetable, *brassica*, head and stem, group 5-16, except cauliflower	2
* * * * * * *	

[1] This tolerance expires on January 24, 2020.

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